DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

August 15, 2014

Choice Spine, LP
Ms. Kim Finch
Manager, Regulatory Affairs
400 Erin Drive
Knoxville, Tennessee 37919

Re: K132049
Trade/Device Name: THUNDERBOLT™ and LANCER™ Pedicle Screw Systems
Regulation Number: 21 CFR 888.3070
Regulation Name: Pedicle screw spinal system
Regulatory Class: Class III
Product Code: NKB, MNH, MNI
Dated: August 1, 2014
Received: August 4, 2014

Dear Ms. Finch:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical

device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mark N. Melkerson -S

Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K132049

Device Name
THUNDERBOLT™ and LANCER™ Pedicle Screw System

Indications for Use *(Describe)*
The THUNDERBOLT™ Minimally Invasive and LANCER™ Open Pedicle Screw Systems are intended to provide immobilization and stabilization of spinal segments in skeletally mature patients as an adjunct to fusion in the treatment of the following acute and chronic instabilities or deformities of the thoracic, lumbar, and sacral spine: degenerative disc disease (DDD; defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies); spondylolisthesis; trauma (i.e., fracture or dislocation); spinal stenosis; deformities or curvatures (i.e., scoliosis, kyphosis, and/or lordosis); tumor; pseudoarthrosis; and failed previous fusion.

When used in a posterior percutaneous approach with MIS instrumentation, the THUNDERBOLT™ System is intended for noncervical pedicle fixation for the following indications: degenerative disc disease (defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies); spondylolisthesis; trauma (i.e., fracture or dislocation); spinal stenosis; deformities; curvatures (i.e., scoliosis, kyphosis, and/or lordosis); tumor, pseudoarthrosis; and failed previous fusion.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

510(k) Summary

Date Prepared:	**Aug 15, 2014**
Submitter Contact:	Kim Finch Choice Spine, LP Manager of Regulatory Affairs 400 Erin Drive, Knoxville, TN 37919 Tel: 865.246.3333 | Fax: 865.588.4045 kfinch@choicespine.net
Regulatory Contact:	Same
Trade Name:	THUNDERBOLT™ and LANCER™ Pedicle Screw System
Product Class:	Class III
Classification:	888.3070 Pedicle Screw Spinal System
Product Codes:	MNI, MNH, NKB
Panel Code:	87

Indications for Use:

The THUNDERBOLT™ Minimally Invasive and LANCER™ Open Pedicle Screw Systems are intended to provide immobilization and stabilization of spinal segments in skeletally mature patients as an adjunct to fusion in the treatment of the following acute and chronic instabilities or deformities of the thoracic, lumbar, and sacral spine: degenerative disc disease (DDD; defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies); spondylolisthesis; trauma (i.e., fracture or dislocation); spinal stenosis; deformities or curvatures (i.e., scoliosis, kyphosis, and/or lordosis); tumor; pseudoarthrosis; and failed previous fusion.

When used in a posterior percutaneous approach with MIS instrumentation, the THUNDERBOLT™ System is intended for noncervical pedicle fixation for the following indications: degenerative disc disease (defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies); spondylolisthesis; trauma (i.e., fracture or dislocation); spinal stenosis; deformities; curvatures (i.e., scoliosis, kyphosis, and/or lordosis); tumor, pseudoarthrosis; and failed previous fusion.

Device Descriptions:

The THUNDERBOLT™ and LANCER™ Pedicle Screw System is an implant device made from titanium alloy TI 6Al 4V-ELI. It is to be implanted from the posterior approach. The screws are available in diameters from 4.5-9.5mm and in lengths from 25-110mm. Rods are available in 5.5mm diameter in lengths from 30-440mm and in an array of configurations including, straight and pre-lordosed configurations. Rods are available in both titanium alloy Ti 6Al 4V-ELI and Cobalt Chrome alloy Co-28Cr-6Mo. The system includes set screws, pedicle screws, cross

connectors and rods along with the associated instrumentation to complete the procedure and implant construct.

Predicate Device(s):
The THUNDERBOLT™ and LANCER™ Pedicle Screw System is substantially equivalent to the previously cleared Choice Spine Starfire (K102204), Pioneer Surgical Streamline (K111502), DePuy Moss Miami (K983583) and U&I Optima (K031585).

Performance Standards:
Performance testing was completed by an independent laboratory following ASTM F1717 and ASTM F1798. The tests included static axial compression bending, static torsion and dynamic axial compression bending. The test results are substantially equivalent to those of the predicate devices.

Conclusion:
Choice Spine concludes that the THUNDERBOLT™ and LANCER™ Pedicle Screw Systems are substantially equivalent to the predicate devices.